DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

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PURGED

cc: ~~HFI-35/FOI Staff~~
DWA

September 18, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-64

Michael Healy
Administrator
Sacred Heart Hospital
501 Summit Street
Yankton, South Dakota 57078

Dear Mr. Healy:

During our recent inspection of your firm, RCS Home Medical Supply Center, a medical oxygen transfiller located in Yankton, SD, our investigator found serious violations of the Current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Oxygen is a drug within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act). Your medical oxygen is adulterated within the meaning of Section 501(a)(2)(B) of the Act.

The violations observed during our inspection include, but are not limited to, the following:

1. Failure to perform the second leak test, referred as the 1800 psi leak test in your standard operating procedures (SOPs).

2. Failure to follow SOPs in that no temperature check is performed on each manifold fill of medical oxygen when your thermometer is being calibrated.

3. Failure to verify identity/purity of the commingled lot when a new cylinder is added to the stand bank.

4. Failure to follow SOP for assigning lot numbers. Your SOP states "lot numbers are determined by using a three digit number ranging from 001 to 999, they are used in sequential order." Your records show lot numbers which are four digits followed by a dash and then another digit, i.e. 1111-1, or a letter, dash, four digits, dash, one digit, i.e. A-1111-1 .

5. Failure to review and document review of production records upon completion.

6. The written SOPs are deficient in that:
   A. There is no description of how or when the calibration of the is performed.

   B. There is no complete description of how labels are received from the gross corporate inventory and added into those received by your firm.

   C. The SOP for the handling of cylinders that have tested unacceptable refers to a reading of 99.01 which is not possible with your analyzer.

It was noted while reviewing the investigator's report that your Transfill SOP is inaccurate in that you state for the D.O.T. test date, "Aluminum Cylinders are (5) Years Steel Cylinders are (10) Years." The test date for the aluminum cylinders is accurate, however, steel cylinders must also undergo testing every five years unless an "*" follows the testing date which means the cylinders may be tested every ten years.

The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Compliance Officer Carrie A. Hoffman at the address indicated on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

CAH/ccl

xc: Mr. Dana D. Jenson
General Manager
RCS Home Medical Supply
400 Park Street
Yankton, South Dakota 57078